

REMARKS

Claims 1-24 are pending. Claims 1-24 stand finally rejected. The claims have been amended to more particularly point out and distinctly claim the subject matter Applicants regard as the invention. Support for the amendments is found in the application as originally filed. No new matter has been added. Applicants respectfully traverse the rejections and request reconsideration and withdrawal of the rejections.

Rejections Under 35 USC 112, Second Paragraph

Claims 12, 13, 20 and 24 stand rejected as being indefinite. Claims 12 and 13 have been amended to clearly recite a lotion free of mineral oil or white soft paraffin. Claims 20 and 24 have also been amended to clearly recite "therapeutically stable." The specification clearly discloses that the invention concerns a therapeutic topical lotion, so one of ordinary skill would understand that claims 20 and 24 are directed to topical lotions that are therapeutically stable for at least 6 months at 40°C. Reconsideration and withdrawal of the rejections is respectfully requested.

Rejections Under 35 USC 103(a)

Claims 1-24 stand rejected as being obvious over WO 92/14472 (the '472 PCT), the Gordon publication, and USPN 4,985,418 (the '418 patent). Applicants respectfully traverse the obviousness rejection because, *inter alia*, no *prima facie* case of obviousness is established by the references.

To establish a *prima facie* case of obviousness, one or more properly combined references must teach each and every element of the claimed invention. The instantly claimed invention is directed to a topical lotion comprising "about 2.0 to 5.0 wt.% of mineral oil or white soft paraffin." (See Claims 1-11, 14-24). The instantly claimed invention is also directed to a lotion "free of mineral oil or white soft paraffin." (See claims 12 and 13).

The '472 PCT discloses various lotion formulations, however only 10.00 %w/w white soft paraffin is disclosed. The '418 patent and the Gordon publication also fail to teach or suggest employing "about 2.0 to 5.0 wt.% of mineral oil or white soft paraffin" or such low amounts of any occlusive agent. The '418 patent is directed to tablet and enema bag dosage forms containing fluticasone propionate and various excipients. The '418 patent fails to disclose any skin conditioning agent or propylene glycol probably because the '418 patent is not directed to topical lotions. Applicants respectfully submit that the '418 patent is non-analogous art because caplet and enema dosage forms are not within the field of endeavor of or pertinent to the problems faced by the ordinary artisan making topical lotions.

The references simply fail to motivate one of ordinary skill to employ low amounts of occlusive agents to improve vasoconstrictor potency or to make the lotion free of mineral oil and white soft paraffin to improve vasoconstrictor potency. Moreover, no *prima facie* case of obviousness is established by alleging optimization because to do so would only be motivated by an attempt "to try" which is insufficient and improper for purposes of obviousness.

The instant specification also discloses that the instant invention has improved vasoconstrictor potency, at least in part, by limiting or eliminating the presence of excessive occlusive agent, such as mineral oil. (See Page 1, lines 27-24).

Thus, the instantly claimed invention is patentably nonobvious over the '472 PCT, the Gordon publication, and the '418 patent because the reference are not properly combinable and because, even if combined, they fail to disclose each and every element of the claimed invention.

Reconsideration and withdrawal of the rejections is respectfully requested.

For the above reasons, Applicants respectfully traverse the rejections set forth in the outstanding Office Action and request that they be withdrawn. Applicants respectfully contend that amendment raises no new issues or

necessitates no additional search. Applicants further submit that the application is in condition for allowance and requests the same. The Examiner is invited to contact the undersigned should there be any questions or concerns.

Respectfully submitted,

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